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PTO/SB/21 (11-07)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM

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Total Number of Pages in This Submission

7

Application Number

10/517,849

Filing Date

July 22, 2005

First Named Inventor

Werner Wessling

Art Unit

4133

Examiner Name

Jeffrey T. Palenik

Attorney Docket Number

RO0957US (#90568)

ENCLOSURES (Check all that apply)



Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)



Reply to Missing Parts/
Incomplete Application



Reply to Missing Parts
under 37 CFR 1.52 or 1.53



Drawing(s)



Licensing-related Papers



Petition



Petition to Convert to a
Provisional Application



Power of Attorney, Revocation



Change of Correspondence Address



Terminal Disclaimer



Request for Refund



CD, Number of CD(s) _____

☐ Landscape Table on CD



After Allowance Communication to TC



Appeal Communication to Board
of Appeals and Interferences



Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)



Proprietary Information



Status Letter



Other Enclosure(s) (please identify
below):

return postcard receipt

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

D. Peter Hochberg Co., L.P.A.

Signature

D. Peter Hochberg

Printed name

D. Peter Hochberg

Date

November 26, 2007

Reg. No.

24,603

CERTIFICATE OF TRANSMISSION/MAILING

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Signature

Sean Mellino

Typed or printed name

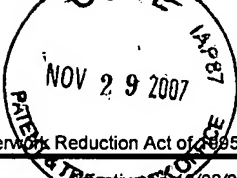
Sean Mellino

Date

11/26/2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Revised 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0.00

Complete if Known

Application Number	10/517,849
Filing Date	July 22, 2005
First Named Inventor	Werner Wessling
Examiner Name	Jeffrey T. Palenik
Art Unit	4133
Attorney Docket No.	RO0957US (#90568)

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☒ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 08-2441 Deposit Account Name: D. Peter Hochberg Co., L.P.A.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayments

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FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
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- 20 or HP = _____ x _____ = _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
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- 3 or HP = _____ x _____ = _____

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
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- 100 = _____ / 50 = _____ (round up to a whole number) x 260.00 = 0.00

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Fees Paid (\$)

Other (e.g., late filing surcharge): _____

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	24,603	Telephone	216-771-3800
Name (Print/Type)	D. Peter Hochberg	Date	November 26, 2007		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Date: Nov. 26, 2007

Sean Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Werner Wessling

Serial No. : 10/517,849 (Conf. No. 1323)

Filing Date : July 22, 2005

Title : FILM-SHAPED, MUCOADHESIVE
ADMINISTRATION FORMS FOR
ADMINISTRATION OF CANNABIS
AGENTS

Examiner : Jeffrey T. Palenik (Art Unit 4133)

Attorney Docket : RO0957US (#90568)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Reply to Office Action Issued October 26, 2007

Dear Sir:

Claims 1-19 and 21-23 are pending in the instant application. The Examiner has concluded that restriction to one of the following three groups is necessary:

- I. Claims 1-8, 17-19 and 21, drawn to a film-shaped mucoadhesive composition containing a cannabis agent.
- II. Claims 9, 11, 12 and 22, drawn to a method for treating conditions of pain by administering said composition.
- III. Claims 10 and 23-25, drawn to a method for treating conditions of pain by administering a composition containing a cannabinoid agent.

- IV. Claims 13, 16, 26 and 33, drawn to a medicinal product comprising a film-shaped, mucoadhesive administration form containing a cannabis agent.
- V. Claims 14, 15, 27 and 28, drawn to a medicinal product that is a film-shaped, mucoadhesive administration form containing a cannabinoid agent.
- VI. Claims 29-32, drawn to a polymer matrix-based, film-shaped, mucoadhesive administration reservoir form containing a cannabis agent.

The Examiner explains in the Office action that the claims do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features since U.S. Patent No. 5,989,535 (Nayak) teaches a mucoadhesive sustained release composition (claim 1) wherein the drug to be delivered can be dronabinol (e.g., tetrahydrocannabinol), an anti-emetic drug (column 4, line 50).

As explained in the Office action (page 3), the Examiner is requiring restriction between the product and process claims. Consequently, the Examiner concludes that the groups are not so linked as to form a single general concept under PCT Rule 13.1 or have corresponding special technical features under PCT Rule 13.2, and therefore the claims lack unity of invention.

The Applicant hereby elects the claims of Group I (which consist of claims 1-8, 17-19 and 21, drawn to a film-shaped mucoadhesive composition containing a cannabis agent) for further prosecution on the merits thereof. However, the Applicant respectfully objects to the instant restriction requirement, *with traverse*.

As noted above, the Examiner states that there is no special technical feature since Nayak '535 teaches a mucoadhesive sustained release composition (claim 1 of Nayak

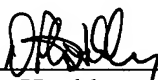
'535) wherein the drug to be delivered can be dronabinol (e.g., tetrahydrocannabinol), an anti-emetic drug (col. 4, line 50). However, the Applicant respectfully submits that Nayak '535 fails to teach a film-shaped administration form, but rather only teaches emulsions, suspensions and the like (e.g., col. 2, lines 1-6; Examples). In addition, Nayak '535 fails to teach "cannabis extract" or "cannabis oil" as set forth in present independent claim 1 (and in the other pending independent claims of the present application).

Therefore, Nayak '535 does not disclose all the special features of the present invention and it is therefore respectfully submitted that the present claims are linked by a single inventive concept according to PCT Rule 13.1.

The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: November 24, 2007

By: 
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